

31 March 2003  
MVE/mcv/465/cor/03-090

Food and Drug Administration  
Docket Management Branch  
HFA – 305  
5630 Fishers Lane – Room 1061  
Rockville Maryland 20582  
USA

**Attention : Docket 02N-0278**

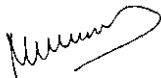
**RE BIO TERRORISM ACT  
SECTION 307 (PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS PROPOSAL)**

Dear Sirs,

The Gelatin Manufacturers of Europe (GME) represents 9 European companies with a total of 18 production plants and accounts for 45% of worldwide gelatine production and as such we would like to comment on the above proposed Regulation for Prior Notice of all Food shipments.

We thank you in advance for your clarifications and hope you will take our comments into consideration.

Yours sincerely



Marc Vermeulen

Appendix (Comments on Section 307)

## **Bio-terrorism Act - Section 307**

### **Prior Notice**

#### **1. General remarks:**

GME would like to support the preliminary stakeholder comments to permit the prior notice to be amended. It would be positive as well if the qualified US agent would be allowed to submit prior notices.

#### **2. Chapter III A „Highlights“ (p. 5430):**

GME has no information about the ACS entry numbers or other US Customs identification numbers which are mandatory for the prior notice submission. Where can the importers or the US agents respectively get these numbers from?

It is our understanding that „all growers“ does not include to list all the farms of origin of the animals which provide the raw materials. According to our interpretation “growers” is only related to plant growing. Is this interpretation correct?

#### **3. „General Provisions“ (p. 5430):**

FDA is requesting comments on whether countries of intermediate destination should also be included in the prior notice. GME thinks that it is important to include the countries of intermediate destination as well, because food may also be manipulated in these countries and the manufacturer/shipper has no influence on this manipulation. The only exception may be food which is transported in sealed containers. Otherwise the food manufacturers will have to prove that this manipulation did not happen in his food processing facility.

In case of articles which can be used for food and non-food, only the food requires prior notice. Does this mean that e.g. technical gelatine (photographic gelatine) does not need a prior notice?

#### **4. Timeframe for prior notices (p. 5434):**

"Prior notices must be submitted no later than noon of the calendar day before...". Does this mean that the former requirement to submit prior notices no less than 8 hours before was deleted? The timeframes should be clearly defined.

#### **5. Amendments/Updates (p. 5438):**

In case of a product change, GME agrees to restrict the number of amendments to one. However, it is not possible to provide the exact "anticipated time of arrival" when transporting food from Europe to the USA (transportation conditions like weather issues or unforeseen traffic). The time of arrival must be updated if it is expected to be more than 1 hour earlier or more than 3 hours later. Therefore, GME would like to request to permit updates of the arrival time as often as necessary.